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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,956	04/06/2006	Steven J. Norris	UTSH:264US/10506328	9208
33425 7590 06/16/2009 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701				
EXAMINER				
SWARTZ, RODNEY P				
ART UNIT		PAPER NUMBER		
1645				
MAIL DATE		DELIVERY MODE		
06/16/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/539,956

**Applicant(s)**

NORRIS, STEVEN J.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/86)  
Paper No(s)/Mail Date 11/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. Applicant's Response to Restriction Requirement, received 23 October 2008, is acknowledged. Applicant elects, without traverse, Invention I, claims 1-16, drawn to DNA, transformed host and method of use.

Claims 17-94 have been cancelled.

2. Claims 1-16 are pending and under consideration.

#### **Priority**

3. It is noted that this application appears to claim subject matter disclosed in prior Applications. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to

submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

#### **Specification**

4. The disclosure is objected to because of the following informalities:

Page 2, line 2, a reference is cited, Wang 2003, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 27, "*Borreliae*" should be "*Borreliae*".

Page 3, line 1, a reference is cited, Iyer et al., 2000, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 3, a reference is cited, Kawabata et al, 1998, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 10, a reference is cited, Labandeira-Ray et al, 2001, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 15, a reference is cited, Lawrenz et al., 1999, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 20, line 33, a reference is cited, Cadavid et al, 1994, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 21, line 2, a reference is cited, Pennington et al, 1997, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 24, line 8, a reference is cited, Jameson and Wolf, 1988, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 9, a reference is cited, Wolf et al., 1988, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 25, line 12, a reference is cited, Jameson and Wolf, 1988, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 12, a reference is cited, Wolf et al., 1988, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 26, line 19, a reference is cited, Harlow and Lane, 1988, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 27, line 23, a reference is cited, Goding, 1986, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 28, line 23, a reference is cited, Kohler and Milstein, 1975; 1976, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 24, a reference is cited, Geftter et al, 1977, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 25, a reference is cited, Goding, 1986, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 36, line 8, a reference is cited, Maloy et al 1994, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 8, a reference is cited, Segal, 1976, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 8, a reference is cited, Prokop, 1991, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages;

line 9, a reference is cited, Kuby, 1994, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 42, line 3, a reference is cited, Kyte and Doolittle, 1982, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 10, a reference is cited, Kyte and Doolittle, 1982, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 46, line 26, a reference is cited, Griffiths et al, 1993, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 48, line 30, a reference is cited, Graham and VanDerEb, 1973, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 31, a reference is cited, Capecchi, 1980, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 31, a reference is cited, Wong and Neumann, 1982, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 31, a reference is cited, Fromm et al 1985, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 32, a reference is cited, Yang et al, 1990, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 32, a reference is cited, Clapp, 1993, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 49, line 1, a reference is cited, Danos and heard,1992, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 1, a reference is cited, Eglitis and Anderson, 1988, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 2 a reference is cited, Wu et al, 1991, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 2, a reference is cited, Curiel et al, 1991, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 2, a reference is cited, Wagner et al 1992, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 6, a reference is cited, Couvreur et al, 1991, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 9, a reference is cited, Gabizon and Paphadjopoulos, 1988, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 10, a reference is cited, Allen and Choun, 1987, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 13, a reference is cited, Henry-Michelland et al, 1987, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 18, a reference is cited, Couvreur et al, 1984, 1988, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 25, a reference is cited, Couvreur et al, 1991, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 51, line 7, "A syrup of elixir" should be "A syrup or elixir".



Page 54, line 28, a reference is cited, Sambrook and Russell, 2000, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 55, line 21, a reference is cited, Sambrook and Russell, 2000, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 58, line 20, a reference is cited, TIGR, 2002, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 59, line 15, a reference is cited, Iyer et al, 2000, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Page 71, line 5, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 75, Page 59, line 15, a reference is cited, Iyer et al, 2000, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages; line 17, a reference is cited, TIGR, 2002, without the required complete disclosure, i.e., author, title, journal, volume, issue, date, and pages.

Appropriate correction is required.

### Drawings

5. M.P.E.P. §2422.02, third paragraph, recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings."

Figures 2A, 2B, 4A and 4B are objected to because they do not contain the required sequence identifier numbers for the sequences displayed.

Appropriate correction is required.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (*ASM*, 100:275, 2000).

The claims are drawn to an isolated nucleic acid comprising a nucleotide sequence that encodes a *vls* peptide of *B. garinii* and a host cell comprising said nucleic acid.

Wang et al teach a cloned 12kB segment of *B. garinii* 1p90 linear plasmid containing *vls* sequences withing Lambda Dash II.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (*FEMS Microbiol. Let.*, 199:39-45, April 2001).

The claim is drawn to an isolated nucleic acid comprising a nucleotide sequence that encodes a *vls* peptide of *B. garinii*.

Wang et al each cloned sequences comprising the *vls* locus of a *B. garinii* isolate which encoded amino acid sequences (Abstract; section **2. Materials and methods**, pages 40-42).

8. Claims 1 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawabata et al (*Microbial Pathogenesis*, 24:155-166, 1998).

The claims are drawn to an isolated nucleic acid comprising a nucleotide sequence that encodes a *vls* peptide of *B. garinii* or *B. afzelii*, and a host cell comprising said nucleic acid wherein said host cell may be *E. coli*.

Kawabata et al teach DNA fragments containing nucleic acid sequence that encodes a *vls* peptide of either *B. garinii* or *B. afzelii* and a host cell, i.e., *E. coli*, which comprising said sequence (Abstract; section "Presence of *vls* gene on the 20-kb ranging plasmid of *B. burgdorferi* and of *vls* homologues in *B. garinii* and *B. afzelii*, page 158-159, Figure 6).

#### **Claim Rejections - 35 USC § 112**

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to any isolated nucleic acid obtained by amplification of a *Borrelia* nucleic acid with a primer selected from a group of 17 SEQ ID Nos.

However, it is unclear what function, if any, is designated by such amplified nucleic acid sequence.

11. Claims 2-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from a rejected claim 1.

**Conclusion**

12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

June 15, 2009